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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,285	08/08/2002	Roland Suck	MERCK 2386	8082

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EXAMINER

SZPERKA, MICHAEL EDWARD

ART UNIT PAPER NUMBER

1644

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,285

Applicant(s)

SUCK ET AL.

Examiner

Michael Szperka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's response and amendment received August 11, 2006 is acknowledged.

Claims 1-8 have been canceled.

Claims 9, 10, 22, 23, 24, and 25 have been amended.

Claims 26-28 have been added.

Claims 9-28 are pending and are under examination in the instant office action.

Applicant's response and amendments received August 11, 2006 have successfully removed all rejections and objections of record. Specifically, the claims as amended would enable a skilled artisan to make and use the claimed method without undue experimentation since the order in which the process steps are to be carried out is positively recited. However, upon reconsideration of the instant claimed invention new grounds of rejection have been set forth as detailed below.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 9 and 24 recite methods wherein an aqueous extract is made, and then "soluble constituents" of the extract are used in further purification steps. What are the "soluble constituents"? It appears that in the working example applicant subjects the entire crude aqueous extract to column chromatography steps without any attempt to first identify or separate "soluble constituents". As such, are the

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"soluble constituents" the entire crude extract or only a portion of the crude extract? If only a portion, how is this portion obtained?

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 9-21, 24, and 26-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant has claimed a broad method by which specific allergens from any and all Gramineae (grass) pollens can be purified. The allergens that can be purified by the recited method include groups 1, 2, 3, 10, and 13. The specification includes a working example wherein said allergens were purified from an aqueous extract of *Phleum pratense*, also known as timothy grass. Dependent claim 10 recites seven specific grasses from which said allergens are to be obtained, one of which is timothy grass.

The taxonomic family of Gramineae comprises more than 600 genera and 10,000 species (Esch, R.E. in Allergens and Allergen Immunotherapy, 3rd edition, pages 185-205, see particularly the top of page 186). The specification discloses where in the prior art information concerning the structure and characterization of group 1, 2, 3, and 10 allergens can be found (see particularly the paragraph spanning pages 1 and 2). It is known in the art that some allergens, such as group 5, are only found in a subset of the members of Gramineae, while other allergens such as group 6 appear to only be found in timothy grass (Esch, pages 194-196). Disclosure of group 13 grass allergens in the art does not appear to have occurred prior to the filing of applicant's instant invention. In the instant application, applicant identified material in a particular fraction as being the group 13 allergen from timothy grass, but structural information such as the amino acid sequence of the allergen, or identification of its function in the plant is not

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disclosed. Note that the determination of if a polypeptide is or is not an allergen is not based upon intrinsic properties of the polypeptide but is instead a context-specific determination since it is known that allergenicity of a polypeptide cannot be determined *a priori* on a structural basis, presumably because the induction of an allergic response is a complicated process involving the interplay of diverse genetic and environmental factors that are not fully understood (Bumenthal et al., in Allergens and Allergen Immunotherapy, pages 37-50, see entire document, particularly the last sentence of the third full paragraph of page 39 and Figures 1 and 2).

The guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, § 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species, then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Fri. January 5, 2001, see especially page 1106 column 3).

In The Regents of the University of California v. Eli Lilly (43 USPQ2d 1398-1412) 19 F. 3d 1559, the court held that disclosure of a single member of a genus (rat insulin) did not provide adequate written support for the claimed genus (all mammalian insulins) and also stated:

"A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin [e] goals appellants hope the claimed invention achieves

and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material."

The court has further stated that "Adequate written description requires a precise definition, such as by structure, formula, chemical name or physical properties, not a mere wish or plan for obtaining the claimed chemical invention." *Id.* at 1566, 43 USPQ2d at 1404 (quoting *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606). Also see *Enzo-Biochem v. Gen-Probe* 01-1230 (CAFC 2002).

As discussed above, the instant application appears to be the first time that group 13 allergens are disclosed, and it is known that many previously identified grass pollen allergens are not present in all Gramineae pollens. As shown in table 1 of Esch, the grass species recited in claim 10 do not appear to be a representative sampling of Gramineae since all of the recited species are found within the subfamily Pooideae. Further, the working example demonstrates that the group 13 allergen can be isolated from timothy grass, but no examples are provided for the other positively recited grass species, and applicant has not disclose the structure of the group 13 allergen that mediates its property of being an allergen in a subset of humans afflicted with grass pollen allergies.

Therefore, it appears that the broad purification method claimed by applicant lacks adequate written description because there does not appear to be any correlation between structure of a group 13 allergen and its role in human allergy. The method also appears to lack adequate written description because the instant disclosure does not provide a representative number of examples of grass pollens that comprise the group 13 allergen since knowledge of this allergen was not known in the prior art and applicant has isolated it only from a single grass species, timothy grass. As such a skilled artisan would reasonably conclude that applicant was not in possession of the claimed purification method that is applicable to the 10,000+ members of the genus of Gramineae pollen at the time the application was filed.

Claim Objections

5. Claims 9 and 24 are objected to because they recite "Graminae" while it appears that the more appropriate nomenclature is Gramineae as is demonstrated by page 186 of Esch.

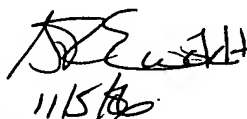
6. No claims are allowable.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Szperka, Ph.D.
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October 31, 2006


11/5/06
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER